

IV. Claim 34, drawn to antisense to CA125, classifiable in class 536, subclasses 24.36 and 24.5.

Responsive to the Requirement for restriction, Applicants elect to prosecute the invention of group I, with traverse, Claims 1-19, 27, and 30-33 drawn to a polypeptide composition. Additionally, Applicant is required under 35 U.S.C § 121 to elect a single disclosed species for prosecution on the merits to which claims shall be restricted if no generic claim is finally held to be allowable. “Specifically, if Group I is elected above, application is required to pick a single combination of amino acid sequences for examination on the merits.”

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C § 121 “two or more independent and distinct inventions . . . in one Application may . . . be restricted to one of the inventions.” Inventions are “independent” if “there is no disclosed relationship between the two or more subjects disclosed” (MPEP 802.01). The term “distinct” means that “two or more subjects as disclosed are related . . . but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER” (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under patent Office Examining Procedures, “[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions” (MPEP 803, Rev. 8, May 1988) (emphasis added).

The Examiner’s assertions to the contrary notwithstanding, Applicants respectfully

submit that conjoint examination and inclusion of all of the Claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the Claims drawn to Group I and Group II is in order.

With respect to the requirement to elect a single species for examination on the merits, Applicants respectfully traverse this requirement for the following reasons:

I. Claim 1(b) providing the multiple repeat domains does not include a genus species relationship

Claim 1(b) relates to a multiple repeat domain. A CA125 molecule can include a variety, if not all of the repeats in a single molecule. SEQ ID NO: 162 which show the recombinant molecule has been marked up as Appendix Tab A, to show the multiple repeats present in a single molecule. Claims to be restricted to different species must be mutually exclusive. The general test as to when claims are restricted respectively to different species is the fact that one claim recites limitations which under the disclosure are found in a first species, but not in a second, while a second claim recites limitations disclosed only from the second species and not the first. MPEP § 12.0[3][c]. As can be seen from an inspection of the recombinant molecule shown in SEQ ID NO: 162, CA125 molecule within the scope of claim 1(b) may have multiple repeat domains which are not mutually exclusive. Consequently, Applicants respectfully request examination on the multiple repeat domains as claimed.

This requirement to elect a single combination of repeats violates the basic right of the Applicants to claim his invention as he chooses. In re Weber, 580 F.2d 455 (USCC 1978).

II. Restriction is not appropriate if the claims are directed to substantially the same molecule

Species are patentably distinct when they are related, but they are capable of separate manufacture and are patentable (novel and nonobvious) over each other. The multiple repeat domains contain multiple repeats wherein each repeat unit has five genomic exons. The variation in repeats set out in Claim 1 (b) are 82% identical and thus present related chemical compounds. The repeat domain is a sequence of 156 amino acids which are repeated multiple times within a discrete portion of the CA125 protein. The repeat domain has its own function and combines with the other domains to provide the overall function of the protein. The

designated exons in the repeat domain can vary, but, this variance is minimal. Importantly, when the nucleic acids are expressed they form a CA125 protein.

Restriction is not appropriate if claims are directed to the same protein.

Applicant hereby elects the following species, with traverse, for prosecution on the merits.

1. A CA125 molecule, comprising:
 - (a) an extracellular amino terminal domain, comprising 5 genomic exons, wherein exon 1 comprises amino acids #1-33 of SEQ ID NO: 299, exon 2 comprises amino acids #34-1593 of SEQ ID NO: 299, exon 3 comprises amino acids #1594-1605 of SEQ ID NO: 299, exon 4 comprises amino acids #1606-1617 of SEQ ID NO: 299, and exon 5 comprises amino acids #1618-1637 of SEQ ID NO: 299;
 - (b) a multiple repeat domain, wherein each repeat unit comprises 5 genomic exons, wherein exon 1 comprises amino acids #1-42 in any of SEQ ID NO: 186; exon 2 comprises amino acids #43-65 in any of SEQ ID NO: 197; exon 3 comprises amino acids #66-123 in any of SEQ ID NO: 244; exon 4 comprises amino acids #124-135 in any of SEQ ID NO: 271; exon 5 comprises amino acids #136-156 in any of SEQ ID NO: 287; and
 - (c) a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain, and further comprising 9 genomic exons, wherein exon 1 comprises amino acids #1-11 of SEQ ID NO: 300; exon 2 comprises amino acids #12-33 of SEQ ID NO: 300; exon 3 comprises amino acids #34-82 of SEQ ID NO: 300; exon 4 comprises amino acids #83-133 of SEQ ID NO: 300; exon 5 comprises amino acids #134-156 of SEQ ID NO: 300; exon 6 comprises amino acids #157-212 of SEQ ID NO: 300; exon 7 comprises amino acids #213-225 of SEQ ID NO: 300; exon 8 comprises amino acids #226-253 of SEQ ID NO: 300; exon 1 comprises amino acids #254-284 of SEQ ID NO: 300.

In view of the above, withdrawal of the Requirement for the Restriction is requested, and an early action on the merits of the Claims is courteously solicited.

Respectfully Submitted,

BUTLER, SNOW, O'MARA,
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Date: 1-13-04

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, on 1-13-04, in a package addressed to: Mail Stop: Art Unit 1635, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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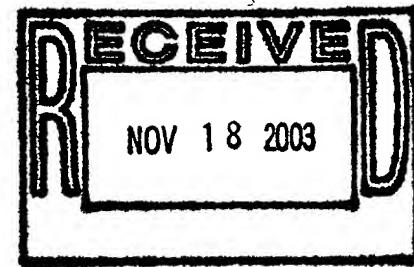
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Please find below and/or attached an Office communication concerning this application or proceeding.



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Butler, Snow, O'Mara

Notice of Non-Responsive Amendment

Applicant's Amendment, filed September 15, 2003 is acknowledged.

Election/Restrictions

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election without traverse of Group I (claims 1-19, 27, and 30-33) is acknowledged. With respect to election of a species, Applicant's election without traverse of the amino acid sequence set out in SEQ ID NO:162 is acknowledged. However, this election of species is non-responsive to the previous Restriction Requirement, filed June 10, 2003 for the following deficiencies: In the previous Restriction Requirement, at page 3, last paragraph, it is explicitly stated that, "Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, if Group I is elected above, Applicant is required to pick a single combination of amino acid sequences for examination on the merits" [emphasis added]. Applicant's election of SEQ ID NO:162 is not a single combination of amino acid sequences for examination, but is instead, the entire coding region of the CA125 gene.

Applicants are required to pick a single combination of amino acid sequences for examination on the merits.

Applicant is reminded, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Since the reply filed on June 11, 2003 appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance with 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
November 7, 2003

Karen Lacourciere
KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER

multiple repeat domain

164
A TVPFMVPFTL NFTITNLQYE EDMRHPGSRK

12101 FNATERELQG 195
12151 RPDPEDLGLD RERLYWELSN LTNGIQELGP YTLDRNSLYV NGFTHRSSMP 222
12201 TTSTPGTSTV DVGTSGTPSS SPSPTAACPL LMPFTENFTI TNLQYEEDMR 278
12251 BCGSRKFNTM ESVLOGILKP LEKNTSVGPL YSGCRKTLR BEKDGAATGV 171
12301 DAICTHRLDP KSPGLNREQL YWELSKLTND IEELGPYTL RNSLYVNGFT 223
12351 HQSSVSTTST 279
12401 LQYGEDMGHP GSRKFNTTER VLQGILGPIF KNTSVGPLYS GORLTSLRSE 173
12451 KDGAAATGVDA ICIHHLDPKS PGLNRERLYW ELSQLTNGIK ELGPYTLDRN 234
12501 SLYVNGFTHR 280
12551 NFTITNLKYE EDMHRPGSRK FNTTERVLTQ 176 202
12601 TLLRSEKDGA ATGVDAICL RLDPKSPGLD REQLYWELSO LTNGIKELGP 235
12651 YTLDNRNSLYV NGFTHWIPVP TSTPGTSTV DLGSQTPSSL PSPTAACPL 267 281
12701 VPFTLNFTIT NLQYEEDMHM PGSRKFNTTE RVLQGILGPM FKNTSVGLLY 182 202
12751 SGCRLLNS EKDGAATGVDA ICTHRLDPK SPGVDRQLY WELSQLTNGI 236
12801 KELGPYTLDR NSLYVNGFTH 263 283
12851 SAGPLLVPT LNFTITNLQY EEDMRHPGSR KFNTTERVLTQ GIKPLFKST 170
12901 SVGPLYSGCR 198 236
12951 QLTNGIKELG PYTLDNRNSLY VNGFTHQTS A PNTSTPGTST VDLGTSGTPS 263 283
13001 SLPSPTISAGP LLVPFTLNFT ITNLQYEEDM HHPGSRKFNT TERVLQGILG 183
13051 PMEKNTSVG 202
13101 LYWEISQLTH GIKELGPYTL DRNSLYVNGF THRSSVAPTS TPGTSTVDLG 256
13151 TSGTPSSLPS 283 165
13201 LQGILGPLFK NSSVGPLYSG CRLISLRSEK DGAATGVDAI CTHHLPQSP 205
13251 GLDREQLYWQ 238 257
13301 STVDLGTSGT 285 177
13351 NATERVLQGL LSPIFKNSSV GPLYSGCR LT SLPEKDGA TGMDAVCLYH 207
13401 PNPKRPGGLDR 227 265
13451 TSTPGTSTVY WATTGTPSSF PGHTEPGPLL IPFTENFTIT NLHYEENMQH 280 186

200
13501 PGSRKFNTE RVLQGILKPL FKNTSVGPLY SGCRSLTSLP EKDGAATGMD
13551 AVCLYHPNPK RPGLDREQLY CELSQLTHNI TELGPYSLDR DSLYVNGFTH
13601 QNSVPTTSTP GTSTVYWATT GTPSSFPGHT EPGPLLIEFT FNFTITNLHY
13651 EENMQHPGSR KFNTTERVLQ GILKPLFKNT SVGPLYSGCR LTLLRPEKHE
13701 AATGVDTICT HRVDPIGPGL DRERLYWELS QLTNSITELG PYTLDRDLSY
13751 VNGFNPRESSV PTSTPSTSTVHATSGTYS-SLPGTAPVPTLEIFFTLNF
13801 ITNLHYEENM QHPGSKKFNTERVLOGGILK PLFKNTSVGFLYSGCRLTLL
13851 RPEKHEAATG VDTICTHRVD PIGPGLDREX LYWELSXLTX XIXELGPYXL
13901 DRXSLYVNGF XXXXXXXXTS TPGTSXVXLX TSGTPXXXPX XTSAGPLLVP
13951 FTLNFTITNL QYEEDMHHPG SRKFNTTERV LQGILGPMFK NTSVGLLYSG
14001 CRLTLLPEKHEAATGMDTITNLQYGE DMRHPGSRKF NTTERVLQGL LGPLFKNSV
14051 LGPYTLDNS LYVNGFTHRS SVAPTSTPGT STVDLGTSGT PSSLPSPTA
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14251 PSPTAGPLL VPFTLNFTIT NLQYEEDMHR PGSRKFNATE RVLQGILSPI
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14351 WELSQLTHNI TELGPYSLDR DSLYVNGFTH QSSMTTRTP DTSTMHLATS
14401 RTPASLSGPT TASPLLVLF INCTITNLQY EEDMRRRTGSR KFNTMESVLO
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14501 NREQLYWELS KLTNDIEELG PYTLDNSLY VNGFTHQSSV STTSTPGTST
14551 VDLRTSGTPS SLSSPTIMXX XPLLXPFTLN FTITNLXYEE XMXXPGSRKF
14601 NTTERVLQGL LRPLFKNTSV SLYSGCRLT LLRPEKDGA TRVDAACTYR
14651 PDPKSPGLDR EQLYWEISQI THSTTEI.GPY TITLQVSTYVNTNPKNSVPT
14701 TSTPGTSTVH LATSGTPSSL PGHTXXXPLL XPFTLNFTIT NLXYEEXMXX
14751 PGSRKFNTE RVLQGILKPL FRNSSLLEYLY SGCRSLTSLP EKDSSAMAVD
14801 AICTHRPDPE DLGLDRERLY WELSNLTNGI QELGPYTLDR NSLYVNGFTH
14851 RSSFLTTSTP WTSTVDLGTS GTPSPVPSPT TAGPLLVPFT LNFTITNLQY

2
16351 NGAATGMDAJ CTHRLDEKSP GLDREXLYWE LSXLTXXIWE LGPYXLDRX~~S~~
16401 LYVNG~~XXXXX~~ XXXXTST~~PGT~~ SXVXLXTSGT~~T~~ PXXXPXXT~~XX~~ XPLLXPFTLN
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16551 TLDNRNSLYVN G~~F~~THR~~R~~SSMPT TST~~PGT~~STV~~D~~ VGTSGTPSSS PSPT~~T~~AGPLL
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19751 RVLQGILXPX FKXTSGXLY SGCRLTLLR EKXXAATXVD XXXCXXXXDPX
19801 XPGLDREXLY WELSXLXXI XELGPYXLDX XSLYVNGFTH 267 WIPVPTSSTP
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20001 XTSTPGTSVX XLXTSGTPXX XPXXTXXXPL LXPFTLNFTI TNLYEEXMX
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20251 GAATRVDAC THRDPKSPG LDREXLYWEL SXLTXXIXEL GPYXLDRXSL
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20351 TITNLHYEEN MQHPGSRKFN TTERVLQGIL 188 RPLFKSTSVG PLYSGCRLTL
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20551 GCRLTLLRPE KRGAAATGVDT ICHRLDPLN PGLDREQLYW ELSKLTRGII 239

20601 ELGPYLLDRG SLYVNGFTHR ²⁶⁰ NFVPITSTPG TSTVH LGTSE TPSSLPRP ²⁹²
20651 PGPLLVPFTL NFTITNLQYE EAMRHPGSRK FNTTERV LQG ¹⁶⁶ ILRPLFKNTS
20701 IGPLYSSCRL TLLRPEKDKA ATRVDAICTH HPDPQSPGLN REQLYWELSQ ²¹² ²⁴⁷
20751 LTHGITE LGP YTLDRD SLYV DGFTHWSPIP TTSTPGTSIV NLGTSGIPPS ²⁶⁸ ²⁹³
20801 LPETT ² KXXPL LXPFTLNFTI TNLXYEEXMX XPGSRKFNTT ERVLQGILK P ¹⁹⁸
20851 LFKSTSVGPL YSGCRLTLLR PEKDGVA TRV DAICTHRPDP KIPGLDRQQL ²³³
20901 YWELS QLTHS ITELGPYTL D RDSLYVNGF QRSSVPTTST PGTFTVQPET ²⁷⁴
20951 SETPSSLPGP TATGPVLLPF TLNFTITNLQ YEEDMHRPGS RKFNTTERVL ²⁹⁴ ¹⁸¹
21001 QGLI ²²⁰ MPPLFKN TSVSSLYSGC RLTLLRPEKD GAATRVDAVC THRPDPKSPG
21051 LDRERLYWKL SQLTHGITE GPYTLDRHSL YVNGFTHQSS MTTTRTPDTS ²³² ²⁶⁰
21101 TMHLATSRTP ASLSGPTTAS PLLVLFTINF TITNLRYEEN MHHPGSRKFN ²⁸⁹ ¹⁸⁵
21151 TTERVLQGIL RPVFKNTSVG PLYSGCRLTL LRPKKDGAAT KVDAICTYRP ²¹⁵
21201 DPKSPGLDRE QLYWELS QLTHS ITELGPY QDRDSLYNVG FTQRSSVPTT ²³¹ ²⁷⁵
21251 SVPGTPTVDL GTSGTPVSKP GPSAASPLLV LFTLNGTITN LRYEENMQHP ²⁹⁵ ¹⁹⁰
21301 GSRKFNTTER VLQGILRSLF KSTSVGPLS GCRLLTLP E KDG TATGVDA ²¹⁶
21351 ICHHHPDPKS PRLDRE QLYW ELSQLTHNIT ELGHYALDND SLFVNGFTHR ²²⁵
21401 SSVSTTSTPG TPTVYL GASK TPASIFGP ²⁵⁵ ASHLLILFTL NFTITNLRYE ²⁹⁰ ¹⁹²
21451 ENMWPGSRKF NTTERVLQGL LRPLFKNTSV GPLYSGSRLT LLRPEKDGEA ²¹¹
21501 TGVD AICTHR PDPTGEGLDR EQLYLELSQL THSITELGPY TLD RDSLYVN ²²⁶
21551 GFTHRSSVPT TSI ²⁵⁴ GVVSEEP FTLNFTINNL RYMADMGQPG SLKFNITDNV ¹⁹³
21601 MKHILSPLFQ RSSLGARYTG CRVIALSVK NGAETRV DLL CTYLOPLSGP ²⁹⁹
21651 GLPIKQVFHE LSQQTHGITR LGPYS LDKDS LYLN ²⁴⁸ NEPG LDEPPTTPKP ²⁷⁶
21701 ATTFLPPLSE ATTAMGYHLK TTLNFTISM LQYSPDMGKG SATFNSTEGV ²⁹⁷ ¹⁹⁴
21751 LQHLLRPLFQ KSSMGPFYLG CQLISLRPEK DGAATGVDTT CTYHPDPVGP ²²¹
21801 GLDIQQLYWE LSQ LTHGVTQ LGFYVLD RDS LFINGYAPQN LSIRGEYQIN ²⁴⁹
21851 FHIVNWNL SN PDPTSSEY ²⁹⁸